K082159

SEP 30 2008

Section 5 - 510(k) Summary

1. Applicant Contact:

Lois V. Smart
Regulatory Consultant
Smart Consulting Services, Inc.
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Date Prepared: July 30, 2008

2.

Name of Device:	CivaString^{Pd103}
Common Name:	Radionuclide Brachytherapy Source
Classification Name:	Brachytherapy Radionuclide Regulation 21 CFR 892.5730, Product Code KXK

3. Identification of device(s) to which the submitted claims equivalence:

The CivaString^{Pd103} is substantially equivalent to the following predicate devices:

- RadioMed™ Source by RadioMed Corporation, 510(k) K001070
- OptiSource^{103} by International Brachytherapy, Inc., 510(k) K040766
- Readi-Strand Model PSStrand by Worldwide Medical Technologies, Inc., 510(k) K023179

4. Device Description:

CivaString^{Pd103} is a linear LDR (low dose rate) brachytherapy source comprised of polymeric materials. CivaString^{Pd103} contains Pd-103 isotope that is distributed into "wells" along the length of the device. Wells may be filled or left empty (to provide gaps in regions where no radiation is desired) based on the overall therapy plan prescription.

5. Intended Use of the Device:

CivaString^{Pd103} is intended for medical purposes to be placed into a body cavity or tissue as a source of nuclear radiation for therapy.

6. Indications for Use

CivaString^{Pd103} is indicated for use as a permanent interstitial brachytherapy source for the treatment of selected localized tumors. The device may be used either as the primary treatment or for treatment of residual disease after excision of the primary tumor. CivaString^{Pd103} may be indicated for use concurrently with or sequentially with other treatment modalities, such as external beam radiation therapy or chemotherapy.

7. Characteristics of the device in comparison to those of the predicate device(s)

When compared with the Intended Use and Indications for Use of the three (3) predicates, the Intended Use and Indications for Use does not change.

The design of each of the predicates and CivaString^{Pd103} is a sealed source from which a therapeutic dosage of radioactive energy is delivered. The predicate devices use a sealed source in a "seed" configuration. CivaString^{Pd103} is a sealed source in the form of a string and is linear versus current point sources.

The energy emitted from CivaString^{Pd103} is exactly the same as current Pd 103 sources: 20-23 keV x-rays.

8. Safety and Performance:

The difference between the CivaString^{Pd103} and the above mentioned predicate devices do not raise any questions regarding the safety and effectiveness of the device. The device, as designed, is as safe and effective as its predicate devices.

9. Conclusion

Based on the design, material, function and intended use discussed herein, CivaTech Oncology, Inc. believes the CivaString^{Pd103} is substantially equivalent to predicate devices currently marketed under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 3 0 2008

CivaTech Oncology, Inc.
% Ms. Lois Smart
Regulatory Consultant
Smart Consulting Services, Inc.
1317 Buchanan Drive
MEBANE NC 27302

Re: K082159
Trade/Device Name: CivaString^{Pd103}
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: July 30, 2008
Received: July 31, 2008

Dear Ms. Smart:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4 - Indications for Use Statement

510k number if known: K082159

Device Name: CivaString^{Pd103}

Indications for Use:

CivaString^{Pd103} is indicated for use as a permanent interstitial brachytherapy source for the treatment of selected localized tumors. The device may be used either as the primary treatment or for treatment of residual disease after excision of the primary tumor. CivaString^{Pd103} may be indicated for use concurrently with or sequentially with other treatment modalities, such as external beam radiation therapy or chemotherapy.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082159